DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 5, 2015

Eli Lilly and Company
c/o Ms. LeeAnn Chambers, M.S., RAC
Global Regulatory Affairs, Devices
Lilly Corporate Center
Indianapolis, Indiana 46285

Re: K142518
Trade/Device Name: HumaPen Luxura
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product code: FMF
Dated: April 10, 2015
Received: April 13, 2015

Dear Ms. Chambers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act.
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must
comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142518

Device Name
HumaPen Luxura

Indications for Use *(Describe)*
HumaPen Luxura is a reusable insulin Pen intended for the self-injection of HUMALOG® (insulin lispro for injection) available in 3 mL Cartridges using disposable Pen Needles (sold separately).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1) **Submitter Information**

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Contact Person: LeeAnn Chambers, M.S., RAC
317-277-1813
chambers_leeann@lilly.com

Date: September 5, 2014

807.92(a)(2) **Device**

Trade Name: HumaPen Luxura

Common Name: Pen-Injector

Classification Name: Piston Syringe

Regulation: 21 CFR 880.5860

Product Code: FMF

Class: II

807.92(a)(3) **Predicate Device**

510(k) Number	Device Name	Submitter Name
K100988	HumaPen Luxura HD	Eli Lilly and Company

807.92(a)(4)

Device Description

The HumaPen Luxura is a reusable mechanical pen-injector designed for use for the self-injection of insulin. The pen-injector is intended for use with Eli Lilly and Company 3 mL insulin cartridges and single-use, detachable and disposable pen needles (supplied separately). The pen injector allows the user to dial the desired dose from 1 to 60 units, one unit at a time.

807.92(a)(5)

Intended Use(s)

HumaPen Luxura is a reusable insulin Pen intended for the self-injection of HUMALOG® (insulin lispro for injection) available in 3 mL Cartridges using disposable Pen Needles (sold separately).

807.92(a)(6)

Technological Characteristics

The HumaPen Luxura is a modification of the predicate device cleared under K100988. Both devices have the same materials of construction but different colors (burgundy and champagne for the new device versus green for the predicate) and different dose increments on the dial (1 unit on the new device dial vs 0.5 unit on the predicate device dial).

Pen Feature	**New Device: HumaPen Luxura**	**Predicate Device: HumaPen Luxura HD K100988**
Similarities		
Intended Use	Delivery of Humalog (insulin lispro for injection) in 3 mL cartridges	Delivery of Humalog (insulin lispro for injection) in 3 mL cartridges
Cartridge Volume	3 ml (300 units of U-100 insulin)	3 ml (300 units of U-100 insulin)
Mechanism	Mechanical pen injector / needle-based injection system	Mechanical pen injector / needle-based injection system
Reusable Device	Yes	Yes
Two-Way Dose Dialing	Yes	Yes
Delivery Accuracy	Meets ISO 11608-1:2012 requirements	Meets ISO 11608-1:2000 requirements
Sterility	Not a sterile device	Not a sterile device
Differences		
Dial Increments	0.01 mL per increment providing one unit (1U) dose increments	0.005 mL per increment providing one half unit (0.5 U) dose increments
Maximum Delivered Dose	60 Units	30 Units

807.92(b)(1) **Non-Clinical Performance Data**

The HumaPen Luxura device meets the requirements specified in ISO 11608-1:2012 *Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems*. The device design has passed the dose accuracy requirements after preconditioning in the following conditions defined in the ISO 11608-1 standard:

- Standard Atmosphere
- Cool Atmosphere
- Warm Atmosphere
- Last-dose Accuracy
- Dry Heat
- Cold Storage
- Free Fall
- Vibration
- Damp Heat
- Temperature cycling (Cyclical)
- Life-cycle test: to support a 6 year in-use life, the sample devices were operated the number of actuations expected for 9 years of operation prior to performing dose accuracy testing.

The HumaPen Luxura is a surface contacting device that contacts intact skin only according to the definitions in ISO 10993-1:2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. The exterior materials of the device were evaluated in accordance with this standard and meet the biocompatibility standard.

The results of Human Factors testing have demonstrated that the HumaPen Luxura is substantially equivalent to the predicate device.

807.92(b)(2) **Clinical Performance Data**

No clinical tests were performed.

807.92(b)(3) **Conclusions**

HumaPen Luxura has met the standards for dose accuracy and functionality identified in the international standard for needle-based injection systems. The device materials meet the biocompatibility standard. Pen operation and pen function are unchanged from the currently cleared HumaPen Luxura HD. All the testing performed demonstrates that the new device is as safe and effective as the predicate device.